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December 31, 2008

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**Re: Medicare Program: Listening Session on Hospital-Acquired
Conditions (HACs) in Inpatient Settings and Hospital Outpatient
Healthcare-Associated Conditions in Outpatient Settings (HOP-HACs),
December 18, 2008**

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide written comments on HACs in Inpatient Settings and HOP-HACs in Outpatient Settings in follow up to the listening session held on December 18, 2008.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology. SHEA works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. SHEA continually strives toward better patient outcomes by applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership in all branches of medicine, public health, and healthcare epidemiology.

SHEA fully supports CMS in its efforts to identify appropriate conditions that should not occur in our hospitals, such as wrong site/wrong patient surgery. As an organization with considerable expertise in the prevention, detection and control [and treatment] of healthcare-associated infections (HAIs), we applaud and share CMS' vision of preventing adverse events in the patients we serve. We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care; however, we believe that steps should be taken to be sure that the implementation timeline is crafted to ensure success, and includes ongoing evaluation of the initiative. Specifically, we believe that CMS needs to verify the feasibility of collecting data related to the initial set of HACs and, even more importantly, to assess evidence related to the risk of unintended negative consequences of implementing the initiative.

Along these lines, we would like to reiterate the following key points made by Tammy Lundstrom, MD, JD, on behalf of SHEA during the CMS Listening Session held on December 18, 2008:

1. **SHEA supports the concept of value-based purchasing.** Aligning reimbursement with the quality of care makes sense and is likely to lead to wider adoption of evidence-based prevention strategies. SHEA agrees that metrics related to quality measures aimed at reducing healthcare associated infections (HAIs) should include process and outcome measures.
2. **In December 2007, CMS indicated its intent to collect data and analyze the implementation of the POA codes and new HAC measures for reimbursement. SHEA believes this is a crucial step to ensure the credibility of this process and to verify the reliability and impact of these initiatives.** This analysis should include careful study of unintended consequences of HAC exclusions.
 - o For example, non-payment for the current HAC, catheter-associated UTI, could lead hospitals to screen patients unnecessarily on admission in an effort to document the presence of bacteria in the urine that is “POA.” Newly hospitalized patients found to have low-grade, asymptomatic bacteruria may then receive unnecessary antibiotic treatment which in turn may fuel the development of infections due to multidrug resistant organisms or *Clostridium difficile*.

Examining any untoward effects of the HAC program will be important to better characterize the impact upon patient care. Moreover, it will be critical to ensure that in an effort to reduce Medicare spending, CMS is not inadvertently driving up overall healthcare costs.

3. **Healthcare-associated infections (HAIs) are better suited to be considered as part of a value-based purchasing model than as “never events”.** Not all infections are universally preventable due to complex issues and the presence of infection risk factors that, unfortunately, may not be reduced through the use of evidenced-based practices (e.g. patient comorbidities such as obesity or immune suppression). Tying payments to conditions that are preventable in some cases, but cannot be completely eliminated even with full implementation of evidence-based measures and/or those for which there are no associated actionable guidelines is unfair to hospitals and misleading to the consumer. We urge the agency to look at other models that incorporate risk adjustment for patient factors (such as age and comorbid conditions) that are inherently associated with the risk of HAI and cannot be modified upon hospital admission. Without this approach, the proposed system would inadvertently build in incentives for healthcare institutions to avoid offering certain procedures or even to avoid providing care to certain patients perceived to be at high risk for infection. Until risk adjustment procedures are defined, SHEA encourages CMS to consider postponing addition of these conditions. When such procedures are defined, these conditions could be integrated into a more robust value-based purchasing (VBP) policy where CMS has the ability to alter payment based on expected rates of these complications.
4. **SHEA encourages CMS to adopt a framework for rule making that is transparent, has a realistic timeline, and emphasizes selection of measures with sufficient evidence base.** We are concerned that CMS is expanding the scope of its policy before current measures are tested and validated, reducing the likelihood of achieving the desired impact on quality and without providing clear information to providers or consumers. We urge an implementation timeline that ensures adequate testing and validation, allows time for institutional process change, and

builds in evaluation of impact. SHEA believes that CMS should create a standardized adoption framework including a timeline that will ensure that conditions included in this policy are truly preventable, rational, do not result in unintended consequences and that hospitals have the necessary practice guidelines and sufficient notice before implementation.

Comments on Proposed Candidate HACs

Surgical Site Infection (SSIs)

SHEA agrees with CMS that it does make sense to build upon the practice of considering the occurrence of selected surgical site infections for consideration as potential indicators of quality of care. Elective, clean or Class I surgeries that have the lowest risk for infection, and may be considered "reasonably preventable" surgical infections are a logical starting point. Our concern remains that categorizing SSIs as HAC reinforces a misperception that ALL SSIs are preventable. Alternatively, we believe that SSI following selected procedures – whether mediastinitis or certain orthopedic procedures – are far better suited to consideration under VBP as risk-adjusted quality measures or for inclusion in the current Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) (treated as other quality measures). Although environmental and care processes can reduce SSI, much remains dependent on patient risk factors. Hospitals typically use the surgical risk index component to CDC's NHSN system designed for surgical surveillance to classify the risk of SSI. Such risk stratification could relatively easily be incorporated into a system of quality measurement.

We believe device or procedure related events such as existing device-related HAIs (e.g., CA-BSI and CA-UTI) should be included in RHQDAPU or proposed VBP program until risk-adjustment can be developed that better reflect inherent patient risks for such infection.

Water Borne Pathogens

Legionnaires' Disease (LD) – We agree with CMS' assessment that LD is often acquired outside the hospital setting through contact with contaminated industrial water systems and may be difficult to diagnose as present upon admission. *Legionella* species are ubiquitous in the environment (soil/water) with regional variations in distribution. As recognized by the CDC, the mere presence of *Legionella* sp. in the water is not necessarily associated with occurrence of disease; a definitive dose-response relationship has not yet been determined, and in the absence of cases of infection, the CDC does not recommend routine culturing of the water.

We, therefore, oppose inclusion of LD in the final IPPS rule as a HAC as it would be punitive to hospitals due to its wider prevalence in the community and the difficulties that exist in diagnosing the disease upon admission. Moreover, we have serious concerns that vendors of water treatment systems may appeal to hospitals' fears of detecting a single organism in hospital water and *inappropriately* encourage routine testing of water systems across the board. In our opinion, this would be a major misuse of resources.

Other Water-Borne Pathogens – SHEA has serious concerns regarding adding this consideration. While LD has been well-studied and remains a challenge, other water-borne pathogens are even less well understood and occur with even less frequency. While SHEA

strongly supports preventive measures to minimize such occurrences, we should not set consumer's expectations for water-related infections as a "never event", leading hospitals to believe they must provide "sterile tap water" or even conduct routine water culturing, to prevent rare and unpredictable events. Linking this to payment without prior field testing, data collection, or reporting is not only premature but risks a major increase in unwarranted healthcare costs.

Ventilator Associated Pneumonia (VAP)

While SHEA strongly believes that this is a serious condition with a negative impact on patient care, we do not support inclusion of this condition at this time and believe that it is premature to link it to non-payment.

The most challenging aspect of VAP continues to be the diagnosis itself. Even post-mortem examination often fails to conclusively determine whether a patient had VAP. In addition, as CMS has clearly noted, VAP has a very low rate of "preventability". Although it is valuable as a measure of internal performance improvement, it is not ready for public reporting or linking to payment. Given the low percentage of cases that are thought to be preventable, SHEA opposes tying this condition to payment.

VAP recently received a new code, so adequate time is needed to evaluate the data and set an appropriate target rate according to our suggested. Also, we are concerned that the codes in the proposed rule "to identify cases in current Medicare data" for VAP suggest that a patient who is on a ventilator (code 96.70-96.72) and has a pneumonia code assumes the patient has VAP. However, some pneumonia codes such as 073.0 (Ornithosis with pneumonia) and 136.3 (Pneumocystosis) would not be routinely associated with a ventilator. The first example is pneumonia developed from an infectious disease that is usually transmitted from birds and the second example is pneumonia due to a fungal organism that is common in the environment and can cause a lung infection in people with weakened immune systems due to conditions such as cancer, HIV or transplant status.

Though we continue to oppose considering VAP an HAC, we do urge CMS to coordinate with other agencies, such as the CDC and other stakeholders, to conduct thorough analysis and field testing to validate the use of this outcome measure, to validate VAP-related "process measures" currently under study, and to ensure that there are clear scientific and measurable prevention guidelines for hospitals to effectively implement. Data may soon be available to determine practices that reliably reduce VAP rates and to help with a choice of where to set a realistic "expected" infection rate.

Clostridium difficile-Associated Disease (CDAD)

There is no question that CDAD causes major harm to patients and is a growing problem due to the growth of epidemic strains in the community. However, questions exist regarding the CDC preventability guidelines and there are concerns in the field regarding the difficulties in quantifying this condition in addition to it not being "reasonably preventable". There is much to learn about how best to collect and report this information, since there many issues related to community-acquired as well as hospital-acquired infection, disease and colonization.

The issue of symptomatic patients being "present on admission" is quite clear; we also agree that outbreaks due to transmission within hospitals are preventable by appropriate infection control precautions. What is not well understood by providers and consumers is that cases will occur after treatment with appropriate antibiotics or even antineoplastics that are necessary to treat underlying conditions. A large proportion of the population is colonized with *C. difficile* but the symptoms of CDAD are only expressed when the individual is being treated for some other condition. Unfortunately, many of these cases will be classified as hospital-acquired since the timing of colonization is unknown. Given the media attention to outbreaks, we believe inclusion of this measure will further reinforce public perception that this should *never* happen –that it is a "never event" – and is 100% preventable. Again, we believe we can work together to determine what may be "reasonably-preventable" but believe it is premature to tie this to reporting much less payment.

HAC Policy for Hospital Outpatient Setting

At the listening session, CMS also solicited comments on the possible application of a payment policy similar to the hospital-acquired conditions provision within the inpatient PPS to the outpatient setting among other areas of care.

While SHEA is deeply committed to quality improvement and supports CMS' effort to begin thinking through the issues associated with applying a similar policy to other payment systems, we urge CMS to first learn from the current inpatient experience with HACs. Implementation of such a policy in the outpatient setting will be exponentially more cumbersome than in the inpatient setting due to the smaller units of payment, inpatient bundling rules, lack of present on admission (POA) coding and other interacting policies. We believe that CMS would be wise to wait until some of the central questions raised under the inpatient PPS such as preventability, risk adjustment, unintended consequences, coding accuracy, burden and affect on overall healthcare costs are resolved before proposing a concrete policy in future rule making.

SHEA joins in your commitment to improving the safety of healthcare and looks forward to working with CMS toward this end.

Sincerely,



Patrick J. Brennan, M.D.
President
Society for Healthcare Epidemiology of America